Appl. No. 10/713,266

Amdt. dated February 21, 2006

Reply to Office action of November 18, 2005

## **REMARKS**

Claims 8, 9, 11, 13, 14, 16, 18 and 19 are presently in the application. Claims 1-7, 10, 12, 15 and 17 have been canceled. Claims 11, 16, 18 and 19 have been withdrawn from further consideration as being directed to nonelected species.

The above amendments are being made to place the application in better condition for examination.

The examiner has required a new title which is clearly indicative of the invention to which the claims are directed. A new title is presented in the above amendments.

Claims 8-10 and 13-15 have been rejected under 35 USC 112, second paragraph, as being indefinite. The claims have been amended to distinguish the distal tip as a positioning tip. In view of the amendments to the claims, withdrawal of the rejection is requested.

In conjunction with the changes in terminology to the claims, corresponding changes to the terminology in the specification have been made. Because of the number of changes required, attached to this amendment is a substitute specification, including a clean copy and a marked up copy showing all of the changes relative to the immediate prior version of the specification. Applicants hereby state that the substitute specification includes no new matter.

Claims 8, 9, 13, and 14 have been rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,997,448 to Filer. Reconsideration of this rejection is respectfully requested.

Filer is relied upon for showing a biodegradable cement sealing plug 2 inserted into an enlarged opening 34 at the top of the bone canal. The plug has a membrane that is punctured by the joint stem tip as it is inserted through the opening into the bone canal bore 31.

Filer also teaches an annular centralizer 42 mounted on the distal end of the stem 40. See Figs. 12, 13 and 17.

Filer neither teaches nor suggests that the annular centralizer 42 is made of a biodegradable and absorbable material or that the means for mounting the annular centralizer 42 on a cementless artificial joint stem at a position near the distal end of the stem is at a position that is offset from the center axis of the annular centralizer, as required by claim 8.

Further, Filer neither teaches nor suggests means for mounting the plug 2 on a cementless artificial joint stem at a position near the distal end of the stem. Rather, Filer teaches that the plug 2 is mounted near the proximal end to the artificial joint. Filer also lacks a teaching or suggestion of a means for mounting the plug on a cementless artificial joint stem offset from the center axis of the plug, as required by claim 8.

To support a rejection of a claim under 35 U.S.C. 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. See Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

Filer neither teaches nor suggests a positioning tip of the type recited in claim 8 in which the tip is made of a biodegradable and absorbable material or that the means for mounting the tip is at a position that is offset from the center axis of the positioning tip.

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Accordingly, claim 8 and dependent claims 9, 13, and 14 are not anticipated by the teachings of Filer.

Claim 9 is even more remote from Filer because it recites that the means for mounting the tip on a cementless artificial joint stem is selected from the group consisting of a fitting hole extending axially through the positioning tip, a fitting protrusion, and a screw that fits with the distal end portion of the stem. None of which is taught by Filer.

Claims 8 and 9 have been rejected under 35 USC 102(e) as being anticipated by US Patent No. 6,916,483 to Ralph et al. Ralph fails to teach means for mounting the tip on a cementless artificial joint stem at a position near the distal end of the stem or that the means for mounting the tip is at a position that is offset from the center axis of the positioning tip, as required by claim 8. Therefore, Ralph et al does not anticipate claims 8 and 9.

Claims 8-10 and 13-15 have been rejected under 35 USC 103(a) as being unpatentable over US Patent No. 5,885,295 to McDaniel et al in view of Ralph et al.

McDaniel et al. is relied upon for showing a positioning jig 36 which engages with a head portion of a hip prosthesis, rather than a positioning means for the distal end portion of the stem. Furthermore McDaniel et al. uses grouting material 106. Ralph et al is combined with McDaniel et al to disclose the use of a biodegradable material. Neither McDaniel et al or Ralph et al teaches or suggests means for mounting the tip on a cementless artificial joint stem at a position near the distal end of the stem.

McDaniel et al also shows a centralizer sleeve 116 having an axial through hole, positioned on the distal end of the stem 110. See col. 6, lines 26-31.

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To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Neither McDaniel et al or Ralph et al teaches or suggests a positioning tip of the type recited in claim 8 in which the tip or centralizer is made of a biodegradable and absorbable material and that the means for mounting the tip is at a position that is offset from the center axis of the positioning tip. Accordingly, claims 8, 9, 13 and 14 are not rendered obvious by the combined teachings of McDaniel et al and Ralph et al.

Claims 8, 9 and 13-14 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 19, 24, and 28 of copending Application No. 10/938,722.

The claims in copending Application No. 10/938,722 call for the tip to be made from "bone supplementing material," while the claims in this application call for the tip to be made from "a biodegradable and absorbable material." These materials are patentably different as they can consist of materials of varying compositions and functionality. For example a bone supplementing material implies that its function is to strengthen a bone, whereas a biodegradable and absorbable material will eventually dissapear and not be present on the bone.

Further, the claims have been amended to recited that the positioning tip including means for mounting the tip on a cementless artificial joint stem at a position near the distal end of the stem and that the means for mounting the tip is at a position that is offset from the

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center axis of the positioning tip, none of which is taught or suggested in Application No. 10/938,722. Reconsideration of the provisional rejection is respectfully requested.

Entry of the amendment is respectfully solicited and reconsideration of the amended claims is requested.

Respectfully submitted,

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